Complete Summary

GUIDELINE TITLE

2002 national guideline on the management of gonorrhoea in adults.

BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline on the management of gonorrhoea in adults. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [20 references]

COMPLETE SUMMARY CONTENT

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Gonorrhoea

GUIDELINE CATEGORY

Diagnosis Management Treatment

CLINICAL SPECIALTY

Infectious Diseases Obstetrics and Gynecology Urology

INTENDED USERS

Physicians

GUI DELI NE OBJECTI VE(S)

To present a national guideline for the management of gonorrhoea in adults

TARGET POPULATION

Men and women in the United Kingdom with gonorrhoea

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. Culture
- 2. Rapid diagnostic test: microscopy (x 1000) of gram stained genital specimens

Treatment/Management

- 1. Recommended regimens: Ciprofloxacin, ofloxacin, or ampicillin plus probenecid
- 2. Alternative regimens: Ceftriaxone, cefotaxime, or spectinomycin
- 3. Pregnancy/breastfeeding: ceftriaxone, cefotaxime, ampicillin plus probenecid, or spectinomycin
- 4. Pharyngeal infection: ceftriaxone, ciprofloxacin, or ofloxacin
- 5. Follow-up assessment
- 6. Contact tracing

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers searched the Cochrane Library 2000 Issue 4 (Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effectiveness, and Cochrane Controlled Trials Register) using the textword "gonorrhoea" and all entries considered.

The guideline developers also completed a Medline search for published articles in any language for the years 1990-2000 (December) using the subject headings "gonorrhea" and "Neisseria gonorrhoeae". The subheadings focused on were: drug therapy, diagnosis, epidemiology, prevention and control, and therapy. All entries in the English language or with abstracts in English were viewed because of the paucity of "clinical trials" or "reviews". Comprehensive reviews of therapy for

gonorrhoea that have employed MEDLINE search strategies are published and include trials up to 1993.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence:

Ιa

• Evidence obtained from meta-analysis of randomised controlled trials

Ιb

• Evidence obtained from at least one randomised controlled trial

Пa

• Evidence obtained from at least one well designed controlled study without randomisation

Hb

• Evidence obtained from at least one other type of well designed quasiexperimental study

 $\Pi\Pi$

• Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

١V

• Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The revision process commenced with authors being invited to modify and update their 1999 guidelines. These revised versions were posted on the website for a 3 month period and comments invited. The Clinical Effectiveness Group and the authors concerned considered all suggestions and agreed on any modifications to be made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations:

A (Evidence Levels Ia, Ib)

 Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation.

B (Evidence Levels IIa, IIb, III)

• Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation.

C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The initial versions of the guidelines were sent for review to the following:

- Clinical Effectiveness Group (CEG) members
- Chairs of UK Regional GU Medicine Audit Committees who had responded to an invitation to comment on them
- Chair of the Genitourinary Nurses Association (GUNA)
- President of the Society of Health Advisers in Sexually Transmitted Diseases (SHASTD)
- Clinical Effectiveness Committee of the Faculty of Family Planning and Reproductive Health Care (FFP).

Comments were relayed to the authors and attempts made to reach a consensus on points of contention with ultimate editorial control resting with the Clinical Effectiveness Group. Finally, all the guidelines were ratified by the councils of the two parent societies.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I-IV) and grades of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

Diagnosis

- The diagnosis is established by the identification of Neisseria gonorrhoea at an infected site.
- Culture offers a readily available, sensitive (>95%), and cheap diagnostic test
 that also allows antimicrobial sensitivity testing. It is currently the method of
 first choice in the United Kingdom. Selective culture media containing
 antimicrobials are often used to reduce contamination. (Jephcott, 1997)
 Antigen detection tests are also available and may have advantages in
 detecting asymptomatic infection and when specimen transportation is
 delayed.
- Rapid diagnostic tests can be performed in addition to culture to facilitate immediate diagnosis and treatment. Microscopy (x 1000) of Gram stained genital specimens allows direct visualization of Neisseria gonorrhoea as monomorphic Gram negative diplococci within polymorphonuclear leucocytes. In men, microscopy of urethral smears is more sensitive in symptomatic (90% to 95%) than in asymptomatic (50% to 75%) patients. (Sherrard & Barlow, 1996) In women, the sensitivity of microscopy of Gram stained endocervical smears is 37% to 50% and urethral smears (20%). (Barlow & Phillips, 1978) Microscopy is not appropriate for pharyngeal specimens.

Specimen collection

Men: urethra; rectal and/or oropharyngeal tests as indicated by sexual activity.

Women: cervix (rotate swab in endocervix) and urethra; rectal and oropharyngeal tests when symptomatic at these sites, when a sexual partner has gonorrhoea and when indicated by the sexual history.

- Direct plating of genital samples and use of transport media both give acceptable results (Jephcott, 1997; FitzGerald & Bedford, 1996) (evidence level IV).
- The use of cervical culture as a single screening test for gonorrhoea has a sensitivity of 85%. Infection at the cervix is present in only 90% of women with gonococcal infection. (Barlow & Phillips, 1978)
- The sensitivity of a single set of tests from anogenital sites is high (>95%).
 To confidently exclude infection in patients who have had recent sexual contact with a confirmed case of gonorrhoea, a second set of tests a few days after the first set should be considered if epidemiological treatment with antimicrobial therapy is not given (evidence level IV). (FitzGerald & Bedford, 1996)

Management

General advice

- Referral to genitourinary medicine for management is strongly encouraged.
- Patients should be given a detailed explanation of their condition with particular emphasis on the long-term implications for the health of themselves and their partner(s). This should be reinforced with clear and accurate written information.
- Patients should be advised to avoid unprotected sexual intercourse until they and their partner(s) have completed treatment and follow up.

Further investigation

• Screening for coincident sexually transmitted infection should routinely be performed in patients with or at risk of gonorrhoea (evidence level III).

Treatment

Indications for therapy

- A positive rapid diagnostic test.
- A positive culture for Neisseria gonorrhoea.
- On epidemiological grounds, if a recent sexual partner has confirmed gonococcal infection.

Recommended treatments (Sexually Transmitted Diseases, 1997; Centers for Disease Control and Prevention, 1998; Bignell, 1996; Echols et al., 1994; Korting & Kollman, 1994; Moran & Zenilman, 1990; Moran & Levine, 1995; Moran, 1996)

Uncomplicated anogenital infection in adults:

Ciprofloxacin 500 mg orally as a single dose (Grade A recommendation)

or

Ofloxacin 400 mg orally as a single dose (Grade A recommendation)

• Ampicillin 2 g or 3 g plus probenecid* 1 g orally as a single dose, where regional prevalence of penicillin resistant Neisseria gonorrhoea <5% (Grade B recommendation).

- Antimicrobial therapy should take account of local patterns of antimicrobial sensitivity to Neisseria gonorrhoea. The chosen regimen should eliminate infection in at least 95% of those presenting in the local community. (FitzGerald & Bedford, 1996)
- Published treatment trials of therapy for gonorrhoea reflect past efficacy to a
 pathogen which demonstrates a progressive drift in antimicrobial sensitivity.
 An increasing number of isolates of Neisseria gonorrhoea showing resistance
 to penicillin, tetracyclines, and ciprofloxacin are identified each year in the
 United Kingdom. (Communicable Disease Report Weekly, 1999; Ison &
 Martin, 1999; Forsyth, Moyes, & Young, 2000) More resistant isolates are
 acquired in the United Kingdom. Continued surveillance of the antimicrobial
 susceptibility of Neisseria gonorrhoea is essential. If ciprofloxacin resistance
 continues to increase and exceeds 5% of isolates, quinolones may longer be
 suitable as first-line treatment for gonorrhoea.
- Imported infection should be presumed penicillin, tetracycline, and possibly quinolone resistant when treated before antimicrobial sensitivity is known.
 Treatment with an alternative regimen using a cephalosporin or spectinomycin* should be considered.
- Recommended treatment regimens do not comprise all effective regimens, but reflect clinical practice in the United Kingdom.

Alternative regimens

Not usually used as first line therapy in United Kingdom. These regimens are very effective (Bignell, 1996; Korting & Kollman, 1994; Moran & Zenilman, 1990; Moran & Levine, 1995) and highly active against penicillin and quinolone resistant strains of Neisseria gonorrhoea (Evidence Level Ia). They are valuable against imported infection and when special considerations apply.

Ceftriaxone 250 mg intramuscularly as single dose (Grade A recommendation)

or

• Cefotaxime 500 mg intramuscularly as single dose (Grade A recommendation)

or

Spectinomycin 2 g intramuscularly as single dose* (Grade A recommendation).

^{*}There may be problems with availability of this drug.

^{*}There may be problems with availability of this drug.

*There may be problems with availability of this drug.

Allergy

Use a recommended treatment from a different class of antimicrobial.

Pregnancy and breast feeding

 Pregnant women should not be treated with quinolone or tetracycline antimicrobials.

Recommended regimens: (Brocklehurst, 2000; Cavenee et al., 1993)

Ceftriaxone 250 mg intramuscularly as single dose (Grade A recommendation)

or

Cefotaxime 500 mg intramuscularly as single dose (Grade A recommendation)

or

 Ampicillin 2g or 3g plus probenecid* 1 g orally as a single dose, where regional prevalence of penicillin resistant Neisseria gonorrhoea <5% (Grade B recommendation)

or

Spectinomycin 2 g intramuscularly as single dose* (Grade A recommendation).

Pharyngeal infection

Recommended treatments: (Bignell, 1996; Moran, 1995)

• Ceftriaxone 250 mg intramuscularly as single dose (Grade B recommendation)

or

Ciprofloxacin 500 mg orally as a single dose (Grade B recommendation)

or

• Ofloxacin 400 mg orally as a single dose (Grade B recommendation).

^{*}There may be problems with availability of this drug.

Single dose treatments using ampicillin or spectinomycin* have a poor efficacy in eradicating gonococcal infection of the pharynx (Bignell, 1996) (Evidence level II).

*There may be problems with availability of this drug.

Co-infection with Chlamydia trachomatis

Genital infection with Chlamydia trachomatis commonly accompanies genital gonococcal infection (up to 20% of men and 40% of women with gonorrhoea). Screening for Chlamydia trachomatis should routinely be performed on adults with gonorrhoea or treatment given to eradicate possible co-infection. (Sexually Transmitted Diseases, 1997; FitzGerald & Bedford, 1996; Centers for Disease Control and Prevention, 1998) Combining effective antimicrobial therapy against Chlamydia trachomatis with single dose therapy for gonococcal infection is particularly appropriate when there is doubt that a patient will return for follow up evaluation.

Sexual partners

Partner notification should be pursued in all patients identified with gonococcal infection, preferably by a trained health advisor in genitourinary medicine. Action and outcomes should be documented. (FitzGerald et al., 1996) Male patients with symptomatic urethral infection should notify all partners with whom they had sexual contact within the preceding 2 weeks or their last partner if longer. Patients with infection at other sites or asymptomatic infection should notify all partners for the preceding 3 months. Sexual partners should be treated for gonorrhoea preferably after evaluation for sexually acquired infection.

Follow up

At least one follow-up assessment is recommended to confirm compliance with therapy, resolution of symptoms and signs, and partner notification (FitzGerald & Bedford, 1996) (Evidence level IV). A test cure is usually performed in United Kingdom practice. Culture tests should be performed at least 72 hours after completion of antimicrobial therapy. (Jephcott, 1997) Infection identified after treatment more commonly indicates re-infection rather than treatment failure. (Lewis et al., 1999)

Definitions:

Levels of Evidence:

Ιa

• Evidence obtained from meta-analysis of randomised controlled trials

Ιb

Evidence obtained from at least one randomised controlled trial

Ha

Evidence obtained from at least one well designed controlled study without randomisation

Hb

 Evidence obtained from at least one other type of well designed quasiexperimental study

 $\Pi\Pi$

• Evidence obtained from well designed non-experimental descriptive studies such as comparative studies, correlation studies, and case control studies

IV

• Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

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C (Evidence Level IV)

- Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.
- Indicates absence of directly applicable studies of good quality.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is graded and identified for select recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis, treatment and management of gonorrhoea infection.

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Clinical Effectiveness Group reminds the reader that guidelines in themselves are of no use unless they are implemented systematically. The following auditable outcome measures are provided:

- At least 95% of cases of genital gonorrhoea should be cured by first line therapy.
- At least 70% of patients with gonorrhoea should attend for at least one follow up visit and have tests of cure performed within 1 month.
- All patients with gonorrhoea should be screened for genital infection with Chlamydia trachomatis or receive presumptive treatment for this infection.
- All patients identified with genital gonorrhoea should have at least one
 documented interview with a health adviser in genitourinary medicine or
 other health professional trained in partner notification and their action
 documented.
- Documented attendance for testing should be achieved for partners from at least 65% of cases of gonorrhoea.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD). 2002 national guideline on the management of gonorrhoea in adults. London: Association for Genitourinary Medicine (AGUM), Medical Society for the Study of Venereal Disease (MSSVD); 2002. Various p. [20 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Aug (revised 2002)

GUIDELINE DEVELOPER(S)

Association for Genitourinary Medicine - Medical Specialty Society Medical Society for the Study of Venereal Diseases - Disease Specific Society

SOURCE(S) OF FUNDING

Not stated

GUI DELI NE COMMITTEE

Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Author: Chris Bignell

Clinical Effectiveness Group (CEG) Members: Keith Radcliffe (Chairman); Imtyaz

Ahmed-Jushuf; Jan Welch; Mark FitzGerald; Janet Wilson

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Conflict of interest: None

GUIDELINE STATUS

This is the current release of the guideline. This guideline updates a previously released version.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available in HTML format from the <u>Association for Genitourinary Medicine (AGUM) Web site</u>. Also available in Portable Document Format (PDF) from the <u>Medical Society for the Study of Venereal Diseases (MSSVD) Web site</u>.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

• UK national guidelines on sexually transmitted infections and closely related conditions. Introduction. Sex Transm Infect 1999 Aug; 75(Suppl 1): S2-3.

Electronic copies: Available in Portable Document Format (PDF) from the <u>Medical Society for the Study of Venereal Diseases (MSSVD) Web site</u>.

The following is also available:

 Revised UK national guidelines on sexually transmitted infections and closely related conditions 2002. Sex Transm Infect 2002; 78:81-2

Print copies: For further information, please contact the journal publisher, <u>BMJ</u> <u>Publishing Group</u>.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on June 15, 2000. The information was verified by the guideline developer on October 13, 2000. This summary was updated by ECRI on June 24, 2002.

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